

thereof. Applicants reserve the right to prosecute the cancelled and non-amended claims in a continuation application. A marked-up version of the claims appears in Appendix A.

**Rejection of Claims 14, 16, 20, 24 and 26 Under 35 U.S.C. § 102(a)**

Claims 14, 16, 20, 24 and 26 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Fikrig *et al.* (WO 97/42325). Claims 14 and 20 have been canceled, therefore, the rejection is moot as applied to claims 14 and 20. Applicants respectfully traverse the rejection as it applies to claims 16, 24 and 26.

Amended claim 16 is now dependent on amended claim 15, which recites that the recombinant FlaA protein comprises an amino acid sequence shown in SEQ ID NO:2. Amended claims 24 and 26 are now dependant upon claim 21, which recites that the recombinant FlaA protein is encoded by a nucleic acid sequence as shown in SEQ ID NO:1.

Fikrig does not teach or suggest SEQ ID NOs:1 and 2 and therefore does not anticipate claims 16, 24 and 26. Applicants note that they have not stated that the FlaA protein is the P37 protein of Fikrig as asserted by the Office Action and have indeed completely differentiated the P37 protein of Fikrig and the claimed FlaA protein. See Response dated June 24, 2002, pages 4-5. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claim 14 under 35 U.S.C. § 102(b)**

Claim 14 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Grodzicki *et al.*, Hansen *et al.*, Johnson *et al.*, or Gassmann *et al.* Claim 14 has been canceled in order to secure allowable claims in the near future. Therefore, the rejection is

**Rejection of Claims 14, 16, 20, 24 and 26 Under 35 U.S.C. §102(a)**

Claims 14, 16, 20, 24 and 26 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Fikrig *et al.* (Immunity). Claims 14 and 20 have been canceled in order to secure allowable claims in the near future. The rejection is therefore moot as applied to claims 14 and 20. Applicants respectfully traverse the rejection as it applies to claims 16, 24 and 26.

Amended claim 16 has been amended to depend from amended claim 15, which recites the recombinant FlaA protein comprises an amino acid as shown in SEQ ID NO:2.

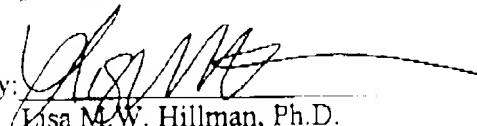
Amended claims 24 and 26 depend from amended claim 21, which recites that the recombinant FlaA protein is encoded by a nucleic acid sequence as shown in SEQ ID NO:1. Fikrig does not teach or suggest SEQ ID NO:1 or SEQ ID NO:2 and therefore cannot anticipate claims 16, 24 and 26. Most importantly, as discussed previously, the P37 protein disclosed by Fikrig is a completely different protein from the claimed FlaA protein. See Applicants' response dated June 24, 2002, pages 6-7.

Applicant respectfully request withdrawal of the rejection.

Respectfully submitted,

Date: October 22, 2002

By:

  
Lisa M.W. Hillman, Ph.D.  
Reg. No. 43,673

**MCDONNELL, BOEHNEN,  
HULBERT & BERGHOFF**  
300 South Wacker Drive  
Chicago, IL 60606

(312) 913 0001

## APPENDIX A

### MARKED-UP VERSION OF CLAIMS TO SHOW CHANGES MADE

15. (Three Times Amended) A diagnostic reagent for early detection of Lyme Disease comprising a recombinant FlaA protein, wherein the [The diagnostic reagent of claim 14, wherein said] protein comprises an amino acid sequence as shown in SEQ ID NO.:2.

16. (Three Times Amended) The diagnostic reagent as in claim [14] 15 wherein said recombinant FlaA protein comprises a fusion protein.

21. (Twice Amended) A diagnostic reagent [as in claim 20 wherein said diagnostic reagent is] for early detection of Lyme disease produced by a method comprising: providing freshly transformed host cells; constructing a DNA expression vector containing an expressible FlaA encoding DNA sequence; transforming a suitable host cell with said expression vector; plating out said transformed host cells; preparing large scale primary cell cultures from transformed host cells taken from a fresh transformant colony; and inducing FlaA protein expression from said host cells in culture to produce a recombinant FlaA protein encoded by a nucleic acid sequence as shown in SEQ ID NO:1.

22. (Twice Amended) A diagnostic reagent as in claim [20] 21 comprising an amino acid sequence as shown in SEQ ID NO:2.

23. (Twice Amended) The recombinant FlaA protein of claim [20] 21 comprising an amino acid sequence encoded by the nucleic acid sequence as shown in SEQ ID NO:3.

24. (Twice Amended) A diagnostic reagent as in claim [20] 21 wherein said recombinant FlaA protein is a fusion protein.

26. (Twice Amended) A diagnostic reagent as in claim [20] 21 wherein said transformed